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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/537,743	11/09/2006	Roberto A. Macina	DEX-0552	4777	
32800 7590 09/24/2008 LICATA & TYRRELL P.C. 66 E. MAIN STREET			EXAMINER		
			MARTINELL, JAMES		
MARLTON, NJ 08053			ART UNIT	PAPER NUMBER	
			1634		
			NOTIFICATION DATE	DELIVERY MODE	
			09/24/2008	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail $\,$ address(es):

poreilly@licataandtyrrell.com

Application No. Applicant(s) 10/537,743 MACINA ET AL. Office Action Summary Examiner Art Unit James Martinell 1634 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 19 August 2008. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-18 is/are pending in the application. 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-10 and 15-18 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 06 June 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date 6/6/05 & 12/3/07.

Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Information Disclosure Statement(s) (PTO/S5/08)

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

Applicant's election with traverse of the requirement for restriction in the reply filed on August 19, 2008 is acknowledged. The traversal is on the ground(s) that a search of the art relating to an elected nucleic acid should reveal art relating to all claims. This is not found persuasive because the searches of the three Groups of inventions are not co-extensive. It is noted that applicants did not argue against the selection of a single sequence for examination on the merits.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-14, 15 (insofar as it is drawn to polypeptide assays) and 16-18 (insofar as they are drawn to kits containing polypeptides (claim 16), methods of treatment using polypeptides (claim 17), and polypeptide vaccines (claim 18)) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 19, 2008.

No copy of WO 042393, cited in the Information Disclosure Statement filed December 3, 2007, is in the file. However, since the reference was readily available to the USPTO, it has been considered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite.

(a) Claims 1-10 and 15-18 are vague and indefinite because they claim more than was elected. Claims 1, 15, 16, and 17 are drawn to or require the use of more than one selected nucleic acid sequence. Claims 15, 16, and 18 are Application/Control Number: 10/537,743 Page 3

Art Unit: 1634

drawn to non-elected methods of using polypeptides, Kits containing polypeptides, and polypeptide vaccines.

(b) Claims 1, 15, and 17 are vague and indefinite because one cannot know any particular percent sequence identity to a nucleic acid that encodes a given polypeptide sequence because of the degeneracy of the genetic code.

Claims 1-10 and 15-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Because one cannot know any particular percent sequence identity to a nucleic acid that encodes a given polypeptide sequence because of the degeneracy of the genetic code, the claims lack an adequate written description in that not enough structure is recited such that one of skill in the art would consider applicants to be in possession of the claimed invention as of the effective filing date of the claims.

In Vas-Cath v Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991) the court stated, "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed" (emphasis in the original) (Vas-Cath at page 1117). The instant application does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now claimed" (Vas-Cath at page 1116). In Fiers v. Sugano, 25 USPQ2d 1601 (Fed. Cir. 1993), the court also held that, "An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference a potential method for isolating it; what is required is a description of the DNA itself" (Fiers v. Sugano, page 1606). This view was reiterated in Fiddes v. Baird, USPQ2d 1481 (BPAI 1993) at page 1483, "If a conception of a DNA requires a specific definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. one cannot describe what one has not conceived." The court amplified this

notion with respect to inventions claiming genetic material in Regents of the University of California v. Eli Lillv. 43 USPO2d 1398 (Fed. Cir. 1997), stating at page 1406.

"In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or mammalian insulin cDNA, 'without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. . . . Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filled in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filled under the treaty defined in section \$51(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the International application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10 and 15-18 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Mitcham et al (WO 00/36107 (June 23, 2000)). Mitcham et al discloses a nucleic acid (SEQ ID NO: 391) that hybridizes to SEQ ID NO: 109 of the instant application (see the alignment below). Mitcham et al also teaches the use of the nucleic acid as a marker for ovarian cancer, treatment of ovarian cancer, and kits for the detection of ovarian cancer (*e.g.*, see the Abstract, page 28, line 15 through page 29, line 20, page 37, lines 11-23, page 42, line 25 through page 44, line 9, page 45, lines 3-10, and page 46, line 1 through page 51, line 20). SEQ ID NO: 109 has basis in Serial No. 60/484,584 (sequence bridging pages 154-155) and thus the effective filing date of the instant claims is June 30, 2003.

ALIGNMENT OF SEQ ID NO: 109 AND MITCHAM ET AL (WO 00/35107, SEQ ID NO: 391)

```
RESHUT 2
AAA70077
ID AAA70077 standard; cDNA; 2627 BP.
XX
AC
    AAA70077;
XX
DT
    07-NOV-2000 (first entry)
XX
DE
    Human ovarian carcinoma antigen polynucleotide SEO ID NO:391.
XX
KW
    Human; ovarian carcinoma; ovarian cancer; therapy; diagnosis;
KW
    tumour antigen; identification; cytostatic; gene therapy; vaccine; ss.
XX
0.5
    Homo sapiens.
XX
    WO200036107-A2.
PN
XX
PD
    22-JUN-2000.
XX
PF
    17-DEC-1999; 99WO-US030270.
XX
    17-DEC-1998; 98US-00215681.
PR
PR
    17-DEC-1998; 98US-00216003.
    23-JUN-1999;
PR
                   99US-00338933.
PR
    24-SEP-1999;
                   99US-00404879.
XX
PA
    (CORI-) CORIXA CORP.
XX
PΙ
    Mitcham JL, King GE, Algate PA, Frudakis TN;
XX
DR
    WPI; 2000-431589/37.
XX
PT
    Immunogenic portion of an ovarian carcinoma protein and the nucleic acid
PТ
    encoding it, useful for the diagnosis, prevention and treatment of
PT
    cancer, preferably ovarian cancer.
XX
    Claim 1; Page 204-205; 299pp; English.
PS
XX
CC
    The present invention describes an isolated polypeptide comprising an
CC
     immunogenic portion of an ovarian carcinoma protein (or its variants).
CC
    Ovarian carcinoma proteins, and polynucleotides encoding them, have
CC
    cytostatic activity and can be used in gene therapy and vaccines. Ovarian
CC
    carcinoma polypeptides, nucleic acids, antibodies and vaccines are useful
CC
    for the prevention, diagnosis and treatment of cancer, preferably ovarian
CC
    cancer. AAA69691 to AAA70077 and AAB12552 to AAB12557 represent human
CC
    ovarian carcinoma polynucleotides and proteins used in the
CC
    exemplification of the present invention
XX
SO
    Sequence 2627 BP; 754 A; 605 C; 584 G; 684 T; 0 U; 0 Other;
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90.5%; Score 2434; DB 3; Length 2627;
Ouery Match
 Best Local Similarity 100.0%; Pred. No. 0;
 Matches 2434; Conservative
                         0; Mismatches
                                       0: Indels
                                                 0: Gans
                                                           0:
       257 CAGGGAGACACTCCATCACAGTCACTACTGTCGCCTCAGCTGGGAACATTGGGGAGGATG 316
Qу
       177 CAGGGAGACACTCCATCACAGTCACTGTCGCCTCAGCTGGGAACATTGGGGAGGATG 236
Db
       317 GAATCCTGAGCTGCACTTTTGAACCTGACATCAAACTTTCTGATATCGTGATACAATGGC 376
       237 GAATCCTGAGCTGCACTTTTGAACCTGACATCAAACTTTCTGATATCGTGATACAATGGC 296
Qv
       377 TGAAGGAAGGTGTTTTAGGCTTGGTCCATGAGTTCAAAGAAGGCAAAGATGAGCTGTCGG 436
       297 TGAAGGAAGGTGTTTTAGGCTTGGTCCATGAGTTCAAAGAAGGCAAAGATGAGCTGTCGG 356
Db
       437 AGCAGGATGAAATGTTCAGAGGCCGGACAGCAGTGTTTGCTGATCAAGTGATAGTTGGCA 496
       357 AGCAGGATGAAATGTTCAGAGGCCGGACAGCAGTGTTTGCTGATCAAGTGATAGTTGGCA 416
       497 ATGCCTCTTTGCGGCTGAAAAACGTGCAACTCACAGATGCTGGCACCTACAAATGTTATA 556
           Dh
       417 ATGCCTCTTTGCGGCTGAAAAACGTGCAACTCACAGATGCTGGCACCTACAAATGTTATA 476
Qу
       557 TCATCACTTCTAAAGGCAAGGGGAATGCTAACCTTGAGTATAAAACTGGAGCCTTCAGCA 616
           477 TCATCACTTCTAAAGGCAAGGGGAATGCTAACCTTGAGTATAAAACTGGAGCCTTCAGCA 536
Dh
       617 TGCCGGAAGTGAATGTGGACTATAATGCCAGCTCAGAGACCTTGCGGTGTGAGGCTCCCC 676
QУ
           Dh
       537 TGCCGGAAGTGAATGTGGACTATAATGCCAGCTCAGAGACCTTGCGGTGTGAGGCTCCCC 596
       677 GATGGTTCCCCCAGCCCACAGTGGTCTGGGCATCCCAAGTTGACCAGGGAGCCAACTTCT 736
           597 GATGGTTCCCCCAGCCCACAGTGGTCTGGGCATCCCAAGTTGACCAGGGAGCCAACTTCT 656
Db
       737 CGGAAGTCTCCAATACCAGCTTTGAGCTGAACTCTGAGAATGTGACCATGAAGGTTGTGT 796
           Dh
       657 CGGAAGTCTCCAATACCAGCTTTGAGCTGAACTCTGAGAATGTGACCATGAAGGTTGTGT 716
       797 CTGTGCTCTACAATGTTACGATCAACACACACATCTCCTGTATGATTGAAAATGACATTG 856
           Db
       717 CTGTGCTCTACAATGTTACGATCAACAACACATACTCCTGTATGATTGAAAATGACATTG 776
       857 CCAAAGCAACAGGGGATATCAAAGTGACAGAATCGGAGATCAAAAGGCGGAGTCACCTAC 916
QУ
Db
       777 CCAAAGCAACAGGGGATATCAAAGTGACAGAATCGGAGATCAAAAGGCGGAGTCACCTAC 836
Qу
       Dh
       977 TTCTGCCTCTCAGCCCTTACCTGATGCTAAAATAATGTGCCTTGGCCACAAAAAAGCATG 1036
       897 TTCTGCCTCTCAGCCCTTACCTGATGCTAAAATAATGTGCCTTGGCCACAAAAAAGCATG 956
Db
       1037 CAAAGTCATTGTTACAACAGGGATCTACAGAACTATTTCACCACCAGATATGACCTAGTT 1096
           957 CAAAGTCATTGTTACAACAGGGATCTACAGAACTATTTCACCACCAGATATGACCTAGTT 1016
Db
```

QУ		TTATATTTCTGGGAGGAATGAATTCATATCTAGAAGTCTGGAGTGAGCAAACAAGAGCA	
Db	1017	TTATATTTCTGGGAGGAAATGAATTCATATCTAGAAGTCTGGAGTGAGCAAACAAGAGC	1076
Qy	1157	AGAAACAAAAGAAGCCAAAAGCAGAAGGCTCCAATATGAACAAGATAAATCTATCT	1216
Db	1077	${\tt AGAAACAAAAGAAGCCAAAAGCAGAAGGCTCCAATATGAACAAGATAAATCTATCT$	1136
Qy	1217	AAGACATATTAGAAGTTGGGAAAATAATTCATGTGAACTAGACAAGTGTGTTAAGAGTGA	1276
Db	1137	AAGACATATTAGAAGTTGGGAAAATAATTCATGTGAACTAGACAAGTGTGTTAAGAGTGA	1196
Qy	1277	${\tt TAAGTAAAATGCACGTGGAGACAAGTGCATCCCCAGATCTCAGGGACCTCCCCCTGCCTG$	1336
Db	1197	TAAGTAAAATGCACGTGGAGACAAGTGCATCCCCAGATCTCAGGGACCTCCCCCTGCCTG	1256
Qy	1337	${\tt TCACCTGGGGAGTGAGAGGACAGGATAGTGCATGTTCTTTGTCTCTGAATTTTTAGTTAT$	1396
Db	1257	TCACCTGGGGAGTGAGAGCAGGATAGTGCATGTTCTTTGTCTCTGAATTTTTAGTTAT	1316
Qy	1397	${\tt ATGTGCTGTAATGTTGCTCTGAGGAAGCCCCTGGAAAGTCTATCCCAACATATCCACATC}$	1456
Db	1317	ATGTGCTGTAATGTTGCTCTGAGGAAGCCCCTGGAAAGTCTATCCCAACATATCCACATC	1376
Qy	1457	${\tt TTATATTCCACAAATTAAGCTGTAGTATGTACCCTAAGACGCTGCTAATTGACTGCCACT}$	1516
Db	1377	TTATATTCCACAAATTAAGCTGTAGTATGTACCCTAAGACGCTGCTAATTGACTGCCACT	1436
Qy	1517	${\tt TCGCAACTCAGGGGCGGCTGCATTTTAGTAATGGGTCAAATGATTCACTTTTTATGATGC}$	1576
Db	1437	TCGCAACTCAGGGGCGGCTGCATTTAGTAATGGGTCAAATGATTCACTTTTATGATGC	1496
Qy	1577	$\tt TTCCAAAGGTGCCTTGGCTTCTCTCCCAACTGACAAATGCCAAAGTTGAGAAAAATGAT$	1636
Db	1497	TTCCAAAGGTGCCTTGGCTTCTCTCCCAACTGACAAATGCCAAAGTTGAGAAAAATGAT	1556
Qy	1637	CATAATTTTAGCATAAACAGAGCAGTCGGCGACACCGATTTATAAATAA	1696
Db	1557	CATAATTTTAGCATAAACAGAGCAGTCGGCGACACCGATTTTATAAATAA	1616
Qy	1697	$\tt TTCTTTTTAAACAAACAAATGCGGGTTTATTTCTCAGATGATGTTCATCCGTGAATGGTC$	1756
Db	1617	TTCTTTTAAACAAACAAATGCGGGTTTATTTCTCAGATGATGTTCATCCGTGAATGGTC	1676
QУ	1757	${\tt CAGGGAAGGACCTTTCACCTTGACTATATGGCATTATGTCATCACAAGCTCTGAGGCTTC}$	1816
Db	1677	CAGGGAAGGACCTTTCACCTTGACTATATGCATTATGTCATCACAAGCTCTGAGGCTTC	1736
Qy	1817	${\tt TCCTTTCCATCCTGCGTGGACAGCTAAGACCTCAGTTTTCAATAGCATCTAGAGCAGTGG}$	1876
Db	1737	TCCTTTCCATCCTGCGTGGACAGCTAAGACCTCAGTTTTCAATAGCATCTAGAGCAGTGG	1796
Qy	1877	${\tt GACTCAGCTGGGGTGATTTCGCCCCCCATCTCCGGGGGAATGTCTGAAGACAATTTTGGT}$	1936
Db	1797	GACTCAGCTGGGTGATTTCGCCCCCCATCTCCGGGGGAATGTCTGAAGACAATTTTGGT	1856
Qy	1937	${\tt TACCTCAATGAGGGAGTGGAGGAGGATACAGTGCTACTACCAACTAGTGGATAAAGGCCA}$	1996
Db	1857	TACCTCAATGAGGGAGTGGAGGAGGATACAGTGCTACTACTAGTGGATAAAGGCCA	1916

ОЛ	1997	GGGATGCTGCTCAACCTCCTACCATGTACAGGACGTCTCCCCATTACAACTACCCAATCC	2056
Db	1917	${\tt GGGATGCTGCTCAACCTCCTACCATGTACAGGACGTCTCCCCATTACAACTACCCAATCC}$	1976
Qy	2057	GAAGTGTCAACTGTGTCAGGACTAAGAAACCCTGGTTTTGAGTAGAAAAGGGCCTGGAAA	2116
Db	1977	${\tt GAAGTGTCAACTGTGTCAGGACTAAGAAACCCTGGTTTTGAGTAGAAAAGGGCCTGGAAA}$	2036
Qy	2117	GAGGGGAGCCAACAAATCTGTCTGCTTCCTCACATTAGTCATTGGCAAATAAGCATTCTG	2176
Db	2037	GAGGGGAGCCAACAAATCTGTCTGCTTCCTCACATTAGTCATTGGCAAATAAGCATTCTG	2096
Qy	2177	${\tt TCTCTTTGGCTGCCTCAGCACAGAGAGCCAGAACTCTATCGGGCACCAGGATAACAT}$	2236
Db	2097	TCTCTTTGGCTGCTCAGCACAGAGAGCCAGAACTCTATCGGGCACCAGGATAACAT	2156
QУ	2237	$\tt CTCTCAGTGAACAGAGTTGACAAGGCCTATGGGAAATGCCTGATGGGATTATCTTCAGCT$	2296
Db	2157	CTCTCAGTGAACAGAGTTGACAAGGCCTATGGGAAATGCCTGATGGGATTATCTTCAGCT	2216
Qy	2297	${\tt TGTTGAGCTTCTAAGTTTCTTTCCCTTCATTCTACCCTGCAAGCCAAGTTCTGTAAGAGA}$	2356
Db	2217	TGTTGAGCTTCTAAGTTTCTTTCCCTTCATTCTACCCTGCAAGCCAAGTTCTGTAAGAGA	2276
QУ	2357	${\tt AATGCCTGAGTTCTAGCTCAGGTTTTCTTACTCTGAATTTAGATCTCCAGACCCTTCCTG}$	2416
Db	2277	AATGCCTGAGTTCTAGCTCAGGTTTTCTTACTCTGAATTTAGATCTCCAGACCCTTCCTG	2336
Qу	2417	${\tt GCCACAATTCAAATTAAGGCAACAAACATATACCTTCCATGAAGCACACACA$	2476
Db	2337	GCCACAATTCAAATTAAGGCAACAAACATATACCTTCCATGAAGCACACACA	2396
QУ	2477	${\tt AAAGCAAGGACAATGACTGCTTGAATTGAGGCCTTGAGGAATGAAGCTTTGAAGGAAAAG}$	2536
Db	2397	AAAGCAAGGACAATGACTGCTTGAATTGAGGCCTTGAGGAATGAAGCTTTGAAGGAAAAG	2456
QУ	2537	${\tt AATACTTTGTTTCCAGCCCCCTTCCCACACTCTTCATGTGTTAACCACTGCCTTCCTGGA}$	2596
Db	2457	AATACTTTGTTTCCAGCCCCTTCCCACACTCTTCATGTGTTAACCACTGCCTTCCTGGA	2516
Qy	2597	$\tt CCTTGGAGCCACGGTGACTGTATTACATGTTGTTATAGAAAACTGATTTTAGAGTTCTGA$	2656
Db	2517	CCTTGGAGCCACGGTGACTGTATTACATGTTGTTATAGAAAACTGATTTTAGAGTTCTGA	2576
QУ	2657	TCGTTCAAGAGAATGATTAAATATACATTTCCTA 2690	
Db	2577	TCGTTCAAGAGAATGATTAAATATACATTTCCTA 2610	

Claims 1-10 and 15-18 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Mitcham et al (U.S. Patent No. 6,468,546). Mitcham et al discloses a nucleic acid (SEQ ID NO: 391) that hybridizes to SEQ ID NO: 109 of the instant application (see the alignment below). Mitcham et al also teaches the use of the nucleic acid as a marker for ovarian cancer, treatment of ovarian cancer, and kits for the detection of ovarian cancer (e.g., see the Abstract, column 8, lines 26-40, column 18, line 34 through column 19, line 51, column 24, lines 36-51, column 28, line 4 through column 29, line 45, and column 30, line 21 through column 33, line 5).

ALIGNMENT OF SEQ ID NO: 109 AND MITCHAM ET AL (U.S. Patent No. 6,468,546, SEQ ID NO: 391)

```
RESULT 1
US-09-404-879A-391
; Sequence 391, Application US/09404879A
; Patent No. 6468546
; GENERAL INFORMATION:
; APPLICANT: Mitcham, Jennifer L.
; APPLICANT: King, Gordon E.
; APPLICANT: Algate, Paul A.
; TITLE OF INVENTION: COMPOSITIONS AND METHODS FOR THE THERAPY AND
; TITLE OF INVENTION: DIAGNOSIS OF OVARIAN CANCER
; FILE REFERENCE: 210121.462C2
; CURRENT APPLICATION NUMBER: US/09/404,879A
  CURRENT FILING DATE: 1999-09-24
; NUMBER OF SEC ID NOS:
                       393
  SOFTWARE: FastSEQ for Windows Version 3.0
; SEQ ID NO 391
   LENGTH: 2627
  TYPE: DNA
  ORGANISM: Homo sapiens
US-09-404-879A-391
 Ouerv Match
                       90.5%; Score 2434; DB 3; Length 2627;
 Best Local Similarity 100.0%; Pred. No. 0;
 Matches 2434; Conservative 0; Mismatches 0; Indels
                                                        0; Gaps
                                                                      0;
Qy
         257 CAGGGAGACACTCCATCACAGTCACTGTCGCCTCAGCTGGGAACATTGGGGAGGATG 316
             Db
         177 CAGGGAGACACTCCATCACAGTCACTGTCGCCTCAGCTGGGAACATTGGGGAGGATG 236
Qv
         317 GAATCCTGAGCTGCACTTTTGAACCTGACATCAAACTTTCTGATATCGTGATACAATGGC 376
```

Ob	237	GAATCCTGAGCTGCACTTTTGAACCTGACATCAAACTTTCTGATATCGTGATACAATGGC	296
ДУ	377	TGAAGGAAGGTGTTTTAGGCTTGGTCCATGAGTTCAAAGAAGGCAAAGATGAGCTGTCG	436
Ob	297	${\tt TGAAGGAAGGTGTTTAGGCTTGGTCCATGAGTTCAAAGAAGGCAAAGATGAGCTGTCGG}$	356
ΣУ	437	AGCAGGATGAAATGTTCAGAGGCCGGACAGCAGTGTTTGCTGATCAAGTGATAGTTGGCA	496
Ob	357	${\tt AGCAGGATGAAATGTTCAGAGGCCGGACAGCAGTGTTTGCTGATCAAGTGATAGTTGGCA}$	416
Σλ	497	ATGCCTCTTTGCGGCTGAAAACGTGCAACTCACAGATGCTGGCACCTACAAATGTTATA	556
Ob	417	${\tt ATGCCTCTTTGCGGCTGAAAAACGTGCAACTCACAGATGCTGGCACCTACAAATGTTATA}$	476
2y	557	TCATCACTTCTAAAGGCAAGGGGAATGCTAACCTTGAGTATAAAACTGGAGCCTTCAGCA	616
Ob	477	${\tt TCATCACTTCTAAAGGCAAGGGGAATGCTAACCTTGAGTATAAAACTGGAGCCTTCAGCA}$	536
ΣÃ	617	TGCCGGAAGTGAATGTGGACTATAATGCCAGCTCAGAGACCTTGCGGTGTAGGCCTCCCC	676
dC	537	${\tt TGCCGGAAGTGAATGTGGACTATAATGCCAGCTCAGAGACCTTGCGGTGTGAGGCTCCCC}$	596
ДУ	677	GATGGTTCCCCCAGCCCACAGTGGTCTGGGCATCCCAAGTTGACCAGGGAGCCAACTTCT	736
Ob	597	${\tt GATGGTTCCCCCAGCCCACAGTGGTCTGGGCATCCCAAGTTGACCAGGGAGCCAACTTCT}$	656
Σy	737	CGGAAGTCTCCAATACCAGCTTTGAGCTGAACTCTGAGAATGTGACCATGAAGGTTGTGT	796
Ob	657	$\tt CGGAAGTCTCCAATACCAGCTTTGAGCTGAACTCTGAGAATGTGACCATGAAGGTTGTGT$	716
ΣÃ	797	CTGTGCTCTACAATGTTACGATCAACACACACATACTCCTGTATGAATGA	856
Ob	717	$\tt CTGTGCTCTACAATGTTACGATCAACAACACATACTCCTGTATGATTGAAAATGACATTG$	776
ДУ	857	CCAAAGCAACAGGGGATATCAAAGTGACAGAATCGGAGATCAAAAGGCGGAGTCACCTAC	916
Ob	777	${\tt CCAAAGCAACAGGGGATATCAAAGTGACAGAATCGGAGATCAAAAGGCGGAGTCACCTAC}$	836
ДĀ	917	AGCTGCTAAACTCAAAGGCTTCTCTGTGTCTCTTTCTTTC	976
Ob	837	${\tt AGCTGCTAAACTCAAAGGCTTCTCTGTGTGTCTCTTTCTT$	896
ΣÃ	977	TTCTGCCTCTCAGCCCTTACCTGATGCTAAAATAATGTGCCTTGGCCACAAAAAAGCATG	1036
Ob	897	${\tt TTCTGCCTCTCAGCCCTTACCTGATGCTAAAATAATGTGCCTTGGCCACAAAAAAGCATG}$	956
ДÄ	1037	CAAAGTCATTGTTACAACAGGGATCTACAGAACTATTTCACCACCAGATATGACCTAGTT	1096
Ob	957	${\tt CAAAGTCATTGTTACAACAGGGATCTACAGAACTATTTCACCACCAGATATGACCTAGTT}$	1016
ДĀ	1097	TTATATTTCTGGGAGGAAATGAATTCATATCTAGAAGTCTGGAGTGAGCAAACAAGAGCA	1156
Ob	1017	${\tt TTATATTCTGGGAGGAAATGAATTCATATCTAGAAGTCTGGAGTGAGCAAACAAGAGCA}$	1076
ДУ	1157	AGAAACAAAAAGAAGCCAAAAGCAGAAGGCTCCAATATGAACAAGATAAATCTATCT	1216
)h	1077	AGAAACAAAAAGAAGCCAAAAGCAGAAGGCTCCAATATGAACAAGATAAATCTATCT	1136

Qy Db		AAGACATATTAGAAGTTGGGAAAATAATTCATGTGAACTAGACAAGTGTGTTAAGAGTGA	
Qy		TAAGTAAAATGCACGTGGAGACAAGTGCATCCCCAGATCTCAGGGACCTCCCCCTGCCTG	
Db	1197		1256
Qy	1337	${\tt TCACCTGGGGAGTGAGAGGACAGGATAGTGCATGTTCTTTGTCTCTGAATTTTTAGTTAT$	1396
Db	1257	TCACCTGGGGAGTGAGAGCAGGATAGTGCATGTTCTTTGTCTCTGAATTTTTAGTTAT	1316
Qy	1397	$\tt ATGTGCTGTAATGTTGCTCTGAGGAAGCCCCTGGAAAGTCTATCCCAACATATCCACATC$	1456
Db	1317	ATGTGCTGTAATGTTGCTCTGAGGAAGCCCCTGGAAAGTCTATCCCAACATATCCACATC	1376
Qy	1457	TTATATTCCACAAATTAAGCTGTAGTATGTACCCTAAGACGCTGCTAATTGACTGCCACT	1516
Db	1377	${\tt TTATATTCCACAAATTAAGCTGTAGTATGTACCCTAAGACGCTGCTAATTGACTGCCACT}$	1436
Qy	1517	TCGCAACTCAGGGCGGCTGCATTTTAGTAATGGGTCAAATGATTCACTTTTTATGATGC	1576
Db	1437	${\tt TCGCAACTCAGGGGCGGCTGCATTTAGTAATGGGTCAAATGATTCACTTTTTATGATGC}$	1496
Qy	1577	TTCCAAAGGTGCCTTGGCTTCTCTCCCAACTGACAAATGCCAAAGTTGAGAAAAATGAT	1636
Db	1497	${\tt TTCCAAAGGTGCCTTGGCTTCTCTCCCAACTGACAAATGCCAAAGTTGAGAAAAATGAT}$	1556
Qy	1637	CATAATTTTAGCATAAACAGAGCAGTCGGCGACACCGATTTTATAAATAA	1696
Db	1557	$\tt CATAATTTTAGCATAAACAGAGCAGTCGGCGACACCGATTTTATAAATAA$	1616
QУ	1697	TTCTTTTTAAACAAACAAATGCGGGTTTATTTCTCAGATGATGTTCATCCGTGAATGGTC	1756
Db	1617	${\tt TTCTTTTTAAACAAACAAATGCGGGTTTATTTCTCAGATGATGTTCATCCGTGAATGGTC}$	1676
QΥ	1757	CAGGGAAGGACCTTTCACCTTGACTATATGGCATTATGTCATCACAAGCTCTGAGGCTTC	1816
Db	1677	${\tt CAGGGAAGGACCTTTCACCTTGACTATATGGCATTATGTCATCACAAGCTCTGAGGCTTC}$	1736
Qy	1817	TCCTTTCCATCCTGCGTGGACAGCTAAGACCTCAGTTTTCAATAGCATCTAGAGCAGTGG	1876
Db	1737	${\tt TCCTTTCCATCCTGCGTGGACAGCTAAGACCTCAGTTTTCAATAGCATCTAGAGCAGTGG}$	1796
Qy	1877	GACTCAGCTGGGGTGATTTCGCCCCCCATCTCCGGGGGAATGTCTGAAGACAATTTTGGT	1936
Db	1797	${\tt GACTCAGCTGGGGTGATTTCGCCCCCCATCTCCGGGGGAATGTCTGAAGACAATTTTGGT}$	1856
Qy	1937	TACCTCAATGAGGGAGTGGAGGAGGATACAGTGCTACTACTAGTGGATAAAGGCCA	1996
Db	1857	${\tt TACCTCAATGAGGGAGTGGAGGAGGATACAGTGCTACTACCAACTAGTGGATAAAGGCCA}$	1916
Qy	1997	GGGATGCTGCTCAACCTCCTACCATGTACAGGACGTCTCCCCATTACAACTACCCAATCC	2056
Db	1917	${\tt GGGATGCTGCTCAACCTCCTACCATGTACAGGACGTCTCCCCATTACAACTACCCAATCC}$	1976
Qy	2057	GAAGTGTCAACTGTGTCAGGACTAAGAAACCCTGGTTTTGAGTAGAAAAGGGCCTGGAAA	2116
Db	1977	GAAGTGTCAACTGTGTCAGGACTAAGAAACCCTGGTTTTGAGTAGAAAAGGGCCTGGAAA	2036

QУ	2117	GAGGGGAGCCAACAAATCTGTCTGCTTCCTCACATTAGTCATTGGCAAATAAGCATTCTG 2176
Db	2037	GAGGGGAGCCAACAAATCTGTCTGCTTCCTCACATTAGTCATTGGCAAATAAGCATTCTG 2096
Qy	2177	TCTCTTTGGCTGCCTCAGCACAGAGAGCCAGAACTCTATCGGGCACCAGGATAACAT 2236
Db	2097	TCTCTTTGGCTGCCTCAGCACAGAGAGCCAGAACTCTATCGGGCACCAGGATAACAT 2156
Qy	2237	CTCTCAGTGAACAGAGTTGACAAGGCCTATGGGAAATGCCTGATGGGATTATCTTCAGCT 2296
Db	2157	CTCTCAGTGAACAGAGTTGACAAGGCCTATGGGAAATGCCTGATGGGATTATCTTCAGCT 2216
QΥ	2297	TGTTGAGCTTCTAAGTTTCTTTCCCTTCATTCTACCCTGCAAGCCAAGTTCTGTAAGAGA 2356
Db	2217	TGTTGAGCTTCTAAGTTTCTTTCCCTTCATTCTACCCTGCAAGCCAAGTTCTGTAAGAGA 2276
Qy	2357	AATGCCTGAGTTCTAGCTCAGGTTTTCTTACTCTGAATTTAGATCTCCAGACCCTTCCTG 2416
Db	2277	AATGCCTGAGTTCTAGCTCAGGTTTTCTTACTCTGAATTTAGATCTCCAGACCCTTCCTG 2336
Qy	2417	GCCACAATTCAAATTAAGGCAACAAACATATACCTTCCATGAAGCACACACA
Db	2337	GCCACAATTCAAATTAAGGCAACAAACATATACCTTCCATGAAGCACACACA
Qy	2477	AAAGCAAGGACAATGACTGCTTGAATTGAGGCCTTGAGGAATGAAGCTTTGAAGGAAAAG 2536
Db	2397	AAAGCAAGGACAATGACTGCTTGAATTGAGGCCTTGAGGAATGAAGCTTTGAAGGAAAAG 2456
Qy	2537	AATACTTTGTTTCCAGCCCCTTCCCACACTCTTCATGTGTTAACCACTGCCTTCCTGGA 2596
Db	2457	AATACTTTGTTTCCAGCCCCTTCCCACACTCTTCATGTGTTAACCACTGCCTTCCTGGA 2516
Qy	2597	CCTTGGAGCCACGGTGACTGTATTACATGTTGTTATAGAAAACTGATTTTAGAGTTCTGA 2656
Db	2517	CCTTGGAGCCACGGTGACTGTATTACATGTTGTTATAGAAAACTGATTTTAGAGTTCTGA 2576
Qy	2657	TCGTTCAAGAGAATGATTAAATATACATTTCCTA 2690
Db	2577	TCGTTCAAGAGAATGATTAAATATACATTTCCTA 2610

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail.

Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla. can be reached on (571) 272-0735.

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